



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILED DATE 25/97	FILE FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

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HM32/1222

EXAMINER SPIEGEL, C	
ART UNIT 1641	PAPER NUMBER 16

DATE MAILED:

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☒ is extended to run _____ or continues to run 3 mos from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).
- ☒ Applicant's response to the final rejection, filed 12/1/98 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
 - b. ☒ They raise new issues that would require further consideration and/or search. (See Note).
 - c. ☐ They raise the issue of new matter. (See Note).
 - d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: see attached

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: none

Claims objected to: none

Claims rejected: 1-9 per Office action mailed 9/2/98 (paper no. 6)

However;

- ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because see attached

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

- ☒ Other 10/27/98 interview summary attached

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The changes to Patent Practice and Procedure published at 62 Fed. Reg. 53131 (October 10, 1997); 1203 Off. Gaz. Pat. Office 63 (October 21, 1997) took effective December 1, 1997. Under these changes new grounds of rejection are prohibited in examiner's answers.

The proposed AMENDMENT AND REMARKS filed December 1, 1998 (paper no. 8) will not be entered and the final rejection stands because the proposed amendment raises new issues that would require further search and/or consideration. As stated in a telephone interview with Ms. Vicki Lorton on October 27, 1998, the outstanding rejection of claims 1, 2, 4 and 6-9 under 35 U.S.C. § 102(b) as clearly anticipated by Imrich et al. (US 5,415,994) would probably change to an obviousness rejection if claims substantially similar to the discussed draft claims were made of record. Since the proposed claims filed December 1, 1998, which are substantially similar to the discussed draft claims; are not sufficient to place the application in condition for allowance; would require further search and consideration of the obviousness of inserting a capillary/immunochromatographic test strip into an extraction mixture; and, therefore, require a new grounds of rejection based upon Imrich et al. and possibly another reference(s), entry of the proposed claims is **denied**.

The Declaration of Richard H. Schwartz under 37 CFR 1.132 filed December 1, 1998 is insufficient to overcome the rejections of claims 1-9 based upon Imrich et al. (US 5,415,994) alone or in combination with Bogart et al. (US 5,494,801) and Murray (US 3,957,436) as set forth in the last Office action because:

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It refer(s) only to the OSOM™ system and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. Moreover, no specifics are provided for the comparative testing with Quidel QuickVue™ In-Line Strep A Test. It is unclear whether this QuickVue™ is identical with Imrich et al. or not. Therefore, the Schwartz Declaration is not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to the examiner's supervisor, James Housel, who can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Carol A. Spiegel
December 21, 1998

Carol A. Spiegel
CAROL A. SPIEGEL
PRIMARY EXAMINER
GROUP 1800 1600